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10/542,506

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John L. Holahan

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POLSTER, LIEDER, WOODRUFF & LUCCHESI  
12412 POWERS COURT DRIVE SUITE 200  
ST. LOUIS, MO 63131-3615

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,506	<b>Applicant(s)</b> HOLAHAN, JOHN L.	
	<b>Examiner</b> D L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 39-45 and 57-89 is/are pending in the application.
- 4a) Of the above claim(s) 57-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/09 &amp; 9/29/09</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 11/23/09 wherein claims 1-38, and 46-56 were canceled; claims 39-42, 44, and 45 were amended; and claims 57-89 were added.

**Note:** Claims 39-45 and 57-89 are pending.

## **RULE 105 REQUEST**

2. The Examiner is making a request for information under 37 CFR 1.105. This requirement for information is deemed necessary because in Applicant's response filed 11/23/09, it was disclosed that "Applicant's assignee sold packets of aqueous thickener concentrate in accordance with the disclosure of its U.S. Patent application 10/485,879 more than one year before the effective filing date of the present application. Therefore, such packaged thickener concentrate is prior art with respect to the present application." As a result, the Examiner is requesting that the product data sheet of the packets of aqueous thickener concentrate as well as instructions regarding process of using of the packages be made of record. The information is necessary in order for the Examiner to determine whether or not the package instructions involved a process wherein the source of aqueous liquid thickener (thickener packages) is in any way in contact with a dispensing machine. Also, applicant is requested to explain the reason for submitting this comment as how it relates to a response to the previous office action.

## **RESPONSE TO APPLICANT'S AMENDMENTS/ARGUMENTS**

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3. The Applicant's arguments and/or amendment filed 11/23/09 to the rejection of claims 39-45 made by the Examiner under 35 USC 102 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

**112 First Paragraph Rejections**

The 112 first paragraph rejections are WITHDRAWN because Applicant amended the claims to overcome the rejections.

**112 Second Paragraph Rejections**

The 112 second paragraph rejections are WITHDRAWN because Applicant amended the claims to overcome the rejections.

**102 Rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 39-41 under 35 U.S.C. 102(b) as being anticipated by Wierlo (US Patent No. 3,839,407) is MAINTAINED.

**Applicant's Assertions:**

In summary, Applicant makes the following assertions (1) the claims are directed to a process of producing a beverage that is suitable for consumption by a person suffering from dysphagia comprising connecting a source of aqueous liquid thickener to a dispensing machine. (2) Wierlo is directed to a blender for making flavored milk-

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shakes and has nothing to do with modifying a beverage dispensing machine. (3) A skilled artisan would recognize that a milkshake melts in the consumer's mouth and would not be suitable for consumption by a person suffering from dysphagia.

**Examiner's Response:**

Applicant response is non-persuasive for the following reasons.

**Wierlo** discloses an apparatus for mixing thickened substances. The apparatus comprises a dispensing nozzle and a combination agitator-mixer-scraper. In addition, Wierlo discloses that unflavored substances such as ice cream, milkshakes, slush, ice, or frozen custard flows toward and exit nozzle the substance comes in contact flavored syrup (see entire document, especially, abstract; column 1, lines 6-13; column 2, lines 15-18). The dispensing machine of Wierlo is selectively dispenses a thickened food (ice cream, frozen custard, milkshake, etc.) into the dispensing nozzle (abstract; column 3, lines 16-35). In the detailed description of the drawings, the details of the apparatus disclose that the dispense machine comprises a compressor motor, various storage tank, and optionally, a pump (column 2, lines 24-46). The dispensing machine has a switch mechanism to allow the operator to regulate the amount of food product being dispensed. Thus, both Applicant and Wierlo disclose a process for the production of a homogenous single phase thickened beverage comprising connecting a thickener to a dispensing machine and a switch mechanism for controlling the amount of thickener present.

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Applicant's independent claim 39 is directed to a process comprising connecting a source of aqueous liquid thickener to a dispensing machine. Thus, the intended use for generating the thickened beverage (to be administered to someone with dysphagia) is not the basis upon which patentability is determined. Specifically, according to MPEP 2111.02, Section II, if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention and the preamble discloses the intended use/purpose of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to the claim construction (*Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F. 3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Circ. 1999)).

## **NEW GROUNDS OF REJECTIONS**

### **112 First Paragraph Rejection (New Matter/Written Description)**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 39-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 39-45: Independent claim 39 has been amended to read 'aqueous liquid thickener'. However, review of the specification indicates that reference is made to an

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‘aqueous liquid’ (see paragraph [0079]), an ‘aqueous based beverage’ (see paragraph [0016]), and a ‘liquid aqueous food’ (see paragraph [0029]), not an ‘aqueous liquid thickener’. Thus, the phrase is believed to be new matter which is not supported by the specification. If Applicant is in disagreement with the Examiner, it is respectfully requested that Applicant point to page(s) and line number(s) wherein support may be found for ‘aqueous liquid thickener’.

As a result of the claims being amended to contain new matter, written description would also be lacking since the instant application does not sufficiently describe the invention as it relates to the aqueous liquid thickener.

Claims 44 and 45: The claims contain new matter because review of the specification does not set forth the ranges appearing in the claims as amended. Applicant is reminded that one cannot neither arbitrarily select endpoints from a range disclosed in the specification nor create a range. Specifically, in claim 44, an endpoint of 1% is not disclosed in the specification. In regards to claim 45, the range 0.3% and 1% of the beverage are not set forth in the disclosure.

### **112 Second Paragraph Rejections**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 39-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 39-45: The claims as written are ambiguous because independent claim 39 has been amended to read 'a source of aqueous liquid thickener'. However, it is unclear if Applicant is referring to an 'aqueous liquid' (see specification paragraph [0079]), an 'aqueous based beverage' (see specification paragraph [0016]), a 'liquid aqueous food' (see specification paragraph [0029]), or the soluble food fiber thickeners of claim 42, for example. Please clarify so that one may readily ascertain what is being claimed.

Claim 41: The claim as written is ambiguous because of the phrase 'sufficient pressure drop'. In particular, it is unclear what pressure drop is necessary in order to obtain the desired results.

### **103 Rejections**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission in view of Wierlo (US Patent No. 3,830,407) and in further view of Uzuhashi et al (US Patent No. 6,455,090).

In Applicant's response filed 11/23/09, the following admission is made.

"Applicant's assignee sold packets of aqueous thickener concentrated in accordance with the disclosure of its US Patent application 10/485,879 more than one year before the effective filing date of the instant invention. Thus, aqueous liquid thickeners are known in the art.

**Wierlo** discloses an apparatus for mixing thickened substances. The apparatus comprises a dispensing nozzle and a combination agitator-mixer-scraper. In addition, Wierlo discloses that unflavored substances such as ice cream, milkshakes, slush, ice, or frozen custard flows toward and exit nozzle the substance comes in contact flavored syrup (see entire document, especially, abstract; column 1, lines 6-13; column 2, lines 15-18). The dispensing machine of Wierlo is selectively dispenses a thickened food (ice cream, frozen custard, milkshake, etc.) into the dispensing nozzle (abstract; column 3, lines 16-35). In the detailed description of the drawings, the details of the apparatus disclose that the dispense machine comprises a compressor motor, various storage tank, and optionally, a pump (column 2, lines 24-46). The dispensing machine has a switch mechanism to allow the operator to regulate the amount of food product being dispensed. Thus, both Applicant and Wierlo disclose a process for the production of a homogenous single phase thickened beverage comprising connecting a thickener to a

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dispensing machine and a switch mechanism for controlling the amount of thickener present.

**Uzuhashi et al** disclose a liquid additive thickener/liquid thickening agent comprising a liquid that is prepared by dissolving a thickening agent into water (see entire document, especially, abstract). In addition, Uzuhashi et al disclose that when (1) the thickening agent is dissolved in a liquid, it retains its fluidity on mixing (column 2, lines 25-27). Also, it is disclosed that Consumers have various preferences as it relates to viscosity and formation of gels for foods. As a result, highly flexible accommodations are needed to meet the individual's needs. Thus, fresh hand-made foods instead of ready-made items that are mass produced as processed foods are required. In order to impart preferable viscosity, for examples, for items such as dressings that adhere to vegetables and sauces for meat and fish dishes, one has to be able to adjust the viscosity of the various items (column 2, lines 37-65). The liquid thickening substance may be utilized in training and nursing facilities to alter the viscosity of food substances for persons with mastication and deglutition difficulties (columns 2-3, bridging paragraph). Possible thickening agents include guar gum, locust bean gum, xanthan gum, sodium carboxymethylcellulose, and carrageenan (column 3, lines 31-37). The thickening agents are prepared as a liquid with a low viscosity that enables it to be dissolved in water (column 3, lines 38-40). Figure 2 discloses a liquid thickening agent that comprises xanthan gum. In one embodiment of Uzuhashi et al, it is disclosed that ten parts by weight of arabic gum were dissolved into 85 parts by weight of water to prepare a solution of arabic gum (Note: this solution yields a total of 95 parts by

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weight). Next, five parts by weight of xanthan gum was added to a solution of arabic gum to prepare a liquid thickening agent (Note: the total parts per weight of the solution is 100 which includes that of the water, arabic gum, and xanthan gum; so, xanthan gum is 5% of the solution). Then, 20 parts by weight of the resultant liquid thickening agent were dissolved into 100 parts by weight of water (Note: the total parts by weight is 120 which includes the thickening agent and the water; so,  $5\% (20) = 1$  which is portion of the thickening agent that is xanthan gum; thus,  $1/120 = 0.008$ . So,  $0.008 (100\%) = 0.8\%$ ) (column 5, lines 5-14). Hence, a skilled artisan would recognize that based upon the teachings of Uzuhashi et al, the xanthan gum is between 1% and 10% of the thickener concentrate and between 0.3% and 1% of the beverage (total solution). Furthermore, Uzuhashi et al disclose that the liquid thickening agent of xanthan gum may be dissolved in milk, consommé soup, salad dressing, and many other items (column 5, lines 15-21).

It would have been obvious to one of ordinary skill in the art to generate a process for the production of a homogeneous thickened beverage comprising connecting a source of aqueous liquid thickener to a dispensing machine for the following reasons. (1) Applicant admits that packets the aqueous liquid thickener packages are known. Therefore, aqueous liquid thickeners are known in the art and were available to the public more than a year before the effective filing date of the present application. (2) It is well known in the art, as indicated by Wierlo, to have a thickened beverage (i.e., milkshake, frozen custard, ice cream, etc.) in contact (i.e., in connection with) with a dispensing machine. (3) Uzuhashi et al disclose motivation for

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one to use a dispensing machine. In particular, the document discloses that the viscosity and formulation of gels of food require that the gels be highly flexible commodities rather than uniform commodities. It is required that fresh hand-made foods with strictly selected materials rather than ready-made commodities that are mass produced as processed foods be generated. In addition, it is disclosed that the gel may be used to impart preferable viscosity of a hand-made dressing, for example, so as to adhere to vegetables. Imparting viscosity in sauces for meat and fish dishes, adjusting viscosity of a liquid starch dressing, and imparting viscosity on a fruit sauce are other examples of items that may have an adjusted viscosity. Further, Uzuhashi et al disclose that the liquid active thickener may be utilized in nursing and training facility (see column 2, lines 38-65 and columns 2-3, bridging paragraph). Therefore, since both the thickener and a dispensing machine connected a thickener are well known in the art, one would be motivated to combine the inventions in order to address the issues set forth by Uzuhashi et al. Specifically, Uzuhashi et al discloses why one would be motivated to generate meals made based on an individual's need (i.e., a person in a nursing or training facility having mastication and deglutition difficulties). Thus, Applicant's admission that the thickener is known and the motivation of Uzuhashi et al to have individualized meals, in combination with a dispensing agent of Wierlo connected to a thickened beverage that may be made to an individual's liking, the skilled artisan would recognize that it is obvious to generate a process of producing a thickened beverage comprising connecting an aqueous liquid thickener to a dispensing machine. Since all of the documents are directed to thickened substances, the

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references may be considered to be within the same field of endeavor. Thus, the reference teachings are combinable.

### **ELECTION BY ORIGINAL PRESENTATION**

11. Newly submitted claims 57-89 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: (see 'Explanation' below).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 57-89 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### **Explanation:**

The newly amended claims are distinct from those presented in claims 39-45 which were previously presented for examination. It is duly noted that Applicant asserts that since the instant application is based off a 371 (PCT) application they are entitled to claims directed to a machine as well as a the method of using the machine in the same application. However, based on the facts of the instant application, one is not entitled to the machine and the method of using the machine simply because the application is based off a PCT (see detailed reasoning in the paragraph(s) below).

In a response to a restriction requirement filed 3/20/09, Applicant cancelled all of the original claims EXCEPT those directed to a process of preparing a product (this was their elected invention). It should be noted that the restriction was based on the

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originally filed claims lacking unity of invention and reasons were set forth as to why in that office action. In the office action filed 7/23/09, I acknowledged Applicant's election of Group V (claims 39-45), use the paragraph regarding the fact that since Applicant did not distinctly and specifically point out the errors in the restriction requirement, it was viewed as an election without traverse.

In Applicant's response filed 11/23/09, the claims were amended to include a machine and uses of the at machine. In addition, the pending claims contain additional process claims that are not requiring process steps that are distinct from those of claims previously presented. Since the Examiner had established that the claims lacked unity of invention, Applicant was no longer entitled to have a machine, use of the machine, and a process examined at one time. Also, it is noted that the machine and use of the machine claims appearing in the amendment filed 11/23/09 were not inventions that were present in the originally filed claims and restricted. Furthermore, based on the rejoinder paragraph (see excerpt below), since Applicant elected the process, not the product, the Examiner is not required to rejoin the inventions.

#### **REJOINDER PARAGRAPH**

The Examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**COMMENTS/NOTES**

12. In paragraph [0077] of the specification, there is an embedded hyperlink and/or other form of browser-executable code. Applicant is respectfully requested to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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13. It should be noted that due to the amending of the claims, modification of the claims listed in the previous 102 rejection as well as new grounds of rejections were necessary in order to address the newly amended claims.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/D L. Jones/  
Primary Examiner  
Art Unit 1618

January 29, 2010